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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|----------------|----------------------|-------------------------|------------------|
| 10/618,975 | 07/14/2003 | Mark D. Soll | MER 03-009 | 8586 |
| 33928 7 | 590 03/23/2006 | | EXAMINER | |
| JUDY JARECKI-BLACK; PH.D., J.D. | | | PRYOR, ALTON NATHANIEL | |
| 3239 SATELLITE BLVD. 3RD FLOOR DULUTH, GA 30096 | | | ART UNIT | PAPER NUMBER |
| Doloin, da | X 30070 | | 1616 | |
| | | | DATE MAILED: 03/23/2006 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|--|--|---|----------------|--|--|--|
| | 10/618,975 | SOLL ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Alton N. Pryor | 1616 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet t | vith the correspondence a | ddress | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period was a specified above. The maximum statutory period was a specified above, the maximum statutory period was a specified above. The maximum statutory period was a specified above, the maximum statutory period was a specified above. The maximum statutory period was a specified above, the maximum statutory period was a specified above. The maximum | ATE OF THIS COMMUN 36(a). In no event, however, may a will apply and will expire SIX (6) MC , cause the application to become | IICATION. a reply be timely filed ONTHS from the mailing date of this of ABANDONED (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | _ | | | | | |
| , | action is non-final. | | | | | |
| 3) Since this application is in condition for allowar | | tters, prosecution as to th | e merits is | | | |
| closed in accordance with the practice under E | · | • | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) 1-63 is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdray | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)☐ Claim(s) is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) <u>1-63</u> are subject to restriction and/or e | election requirement. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examine | r. | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ acce | | by the Examiner. | | | | |
| Applicant may not request that any objection to the | | • | | | | |
| Replacement drawing sheet(s) including the correct | ion is required if the drawin | g(s) is objected to. See 37 C | FR 1.121(d). | | | |
| 11) The oath or declaration is objected to by the Ex | aminer. Note the attache | ed Office Action or form P | TO-152. | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) ☐ Acknowledgment is made of a claim for foreign a) ☐ All b) ☐ Some * c) ☐ None of: | • | § 119(a)-(d) or (f). | | | | |
| | 1. Certified copies of the priority documents have been received. | | | | | |
| 2. Certified copies of the priority documents | | • • | l Ctoro | | | |
| 3. Copies of the certified copies of the prior application from the International Bureau | | in received in this National | Stage | | | |
| * See the attached detailed Office action for a list | . , , , , , , , , , , , , , , , , , , , | at received | | | | |
| | or the certified copies ne | TTOOCIVCU. | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) | , | Summary (PTO-413) | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | | o(s)/Mail Date Informal Patent Application (PT | (O-152) | | | |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | 6) Other: | · | ○ .02 j | | | |

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-24.42-44,63 drawn nodulisporic acid compound and to spot on formulation comprising a nodulisporic acid derivative, carrier, and optionally a crystallization inhibitor, classified in class 514, subclass 410, class 548 subclass 417.
- II. Claims 25-41,45,46,48-52, drawn to method of applying to mammals, fish, birds a composition comprising an nodulisporic acid derivative to treat parasite infestation, classified in class 514, subclass 410.
- III. Claim 47, drawn to method of obtaining a detectable plasma concentration of parasiticides comprising applying to the mammal a formulation comprising nodulisporic acid derivative, classified in class 514, subclass 410.
- IV. Claims 53-62, drawn to preparing compounds of formula I, classified in class 548, subclass 417.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another process.

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Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process for using the product can be practiced with another product.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the process for using the product can be practiced with another product.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions modes of operation.

Inventions II-III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions modes of operation.

Inventions VI and I are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs,

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modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different designs.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

A telephone call was made to Dr. Jarecki-Black on 3/17/06 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

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record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Alton Pryor

Primary Examiner

AU 1616